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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,258	11/03/2005	Paul Goldsmith	0380-P03627US0	1424

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EXAMINER	
BERTOGLIO, VALARIE E	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,258	GOLDSMITH ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *preliminary amendement dated 05/31/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *36-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted..

Group I, claim(s) 1-10,14-16,18,21-22,24-29 drawn to a method of screening for a first gene or substance that affects activity of a second gene using a fish that is transgenic for a second gene where in the second gene affects an aspect of behavior or physiology of the fish.

Group II, claim(s) 1-9,14-18,21-22,24-29 drawn to a method of screening for a first gene or substance that affects activity of a treatment using a fish that is subject to a treatment wherein the treatment affects an aspect of behavior or physiology of the fish.

Group III, claim(s) 19,20 and 21 drawn to a method of screening for test compound that affects activity of a first gene, said first gene affecting activity of a second gene, wherein the second gene affects an aspect of behavior or physiology of a fish and formulating said test compound into a composition.

Group IV, claim(s) 30-35, drawn to a method of determining synergy between two substances or genes that affect activity of a transgene in a fish that is transgenic for a gene of interest wherein the gene of interest affects an aspect of behavior or physiology of the fish.

Group V, claim(s) 30-35, drawn to a method of determining synergy between two substances or genes that affect activity of a treatment using a fish that is subject to a treatment wherein the treatment affects an aspect of behavior or physiology of the fish.

Claims 36-38 are withdrawn and are not considered in the instant restriction requirement because they are wholly unclear. The phrase "the gene of interest" at lines 8-9 of claim 36 lacks antecedent basis. Thus, it is not clear whether "the gene of interest:" is the second "drug target of interest" in the preamble of the claim or is some other gene. If "the gene of interest" is the latter-

mentioned "drug target of interest" of the preamble, then it appears that claim 36 would fit with Groups I and II as a similar method of screening for a first gene or substance wherein the first gene or substance is on that lessens side effects of the 2nd gene or treatment. However, the claim could also be interpreted as a second round of screening for a substance that reduces the side effects of the product identified in a screen such as that of Groups I or II. This latter interpretation would render claims 36-38 in a separate and distinct group. Upon clarification, claims 36-38 will be grouped as deemed appropriate.

Claims 39-42 are withdrawn and are not considered in the instant restriction requirement because they are wholly unclear. How the claims relate to claim 1 us not clearly set forth. Claim 39 is drawn to a method according to claim 1, which is a method of screening a gene or substance, wherein a gene or mutation is identified for a patient population which is more likely to respond to a particular drug, etc. Is it not clear how the "a gene or mutation" of claim 39 relates to the method of claim 1. It is not clear how claims 39-42 further limit the method of claim 1.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different categories of inventions will only be found to exist if the specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. In the instant case, the groups are drawn to multiple, distinct methods. Groups I and II are drawn to methods of using two different products, a transgenic fish (Group I) and a non-transgenic fish (Group II). Group III is drawn to a method of screening for a modulator of a gene or substance identified in the methods of either Group I or II, which is a different method from either that of Group I or Group II. Group IV is drawn to a method of testing for synergy between compounds using a transgenic model fish that is different from the methods of Groups I-III. Group V is drawn to a method of testing for synergy between compounds using a non-transgenic model fish that is different from the methods of Groups I-IV.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VI, do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Groups I and IV is a transgenic fish having altered behaviour or physiology. The "special technical feature" of Groups II and V is a non-transgenic, substance-treated fish having altered behavior or physiology. The

"special technical feature" of Group III is the "first gene". Thus, there appears to be no corresponding technical feature common to all groups.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632